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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/079,478	02/19/2002	L. Curtis Hannah	UF-178AXC2	7981

23557 7590 02/24/2004

SALIWANCHIK LLOYD & SALIWANCHIK
A PROFESSIONAL ASSOCIATION
2421 N.W. 41ST STREET
SUITE A-1
GAINESVILLE, FL 326066669

EXAMINER	
KUBELIK, ANNE R	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/079,478	HANNAH ET AL.	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 42-84* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 42-84* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1 and 42-84 are pending.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The rejection of claims 1, 3, 5-9, 10-13, 20-26 and 30-41 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn in light of Applicant's amendments to the claims.

4. The rejection of claim 1 under 35 U.S.C. 102(b) as being clearly anticipated by Ballicora et al (1995, Plant Physiol. 109:245-251) is withdrawn in light of Applicant's amendments to the claim to limit it large subunits.

Claim Rejections - 35 USC § 112

5. Claims 1, 42-51 and 53-84 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for certain polynucleotides that encode heat stable ADP-glucose pyrophosphorylase (AGP) large subunits from maize, does not reasonably provide enablement for polynucleotides encoding heat stable AGP large subunit mutant enzymes from other plants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is repeated for the reasons of record as set forth in the Office action mailed 8 August 2003, as applied to claims 1, 3, 5-26 and 29-41. Applicant's arguments filed 11 December 2003 have been fully considered but they are not persuasive.

Applicant urges that claim 1 recites that the protein is a plant ADP-glucose pyrophosphorylase large subunit (response pg 12).

This is not found persuasive because description of the function of the protein encoded by the polynucleotide does not teach the sequence of the polynucleotide.

Applicant urges that sequences of large subunit AGP for numerous plant species were well known in the art prior to the earliest effective filing date of the instant application and that a plant need not teach what is well known in the art (response pg 12-13).

This is not found persuasive. A search of GenBank found no entries for sequences of nucleic acids encoding the ADP large subunits from all of oats, sorghum, lily, millet, pea, alfalfa, chickpea, chicory, clover, kale, lentil, soybean, tobacco, sweet potato, radish, cabbage, rape, apple tree and lettuce prior to the earliest effective filing date of the instant application. It is suggested that applicant provide evidence that the sequences for all these plants were publicly available at filing.

Applicant urges that the sequence alignment in Figure 2 the amino acids for wheat and barley corresponding to His^{333} of maize large ADP were known in the art (response pg 13).

This is not found persuasive because the claims are drawn to mutations at amino acids other than His^{333}.

Additionally, Table 3 shows that the $His^{333} \rightarrow Gly^{333}$ mutation in maize actually results in a less heat stable enzyme that the wild-type enzyme. Thus, transformation of a plant with an AGP mutant gene comprising such a mutation could not increase the heat stability of the plant.

Applicant urges that Figure 2 shows there is extensive homology between maize, wheat and barley sequences (response pg 13).

This is not found persuasive because no guidance is provided for the sequences of nucleic acids encoding the ADP large subunit from all of oats, sorghum, lily, millet, pea, alfalfa, chickpea, chicory, clover, kale, lentil, soybean, tobacco, sweet potato, radish, cabbage, rape, apple tree and lettuce.

AGP enzymes from different plants have different lengths and sequences, and so none except the maize enzyme would possess the specified wild type amino acid at the positions specified in claims 6-21 and 32-35. For example, the alanine in bold in Figure 5A of the instant specification is located at amino acid 177 in the maize large subunit AGP, amino acid 183 in the wheat large subunit AGP, amino acid 184 in the barley large subunit AGP, and amino acid 179 in the rice large subunit AGP (Bhave et al, GenBank Accession No. P55241; Ainsworth et al, GenBank Accession No. S60572, Villand et al, GenBank Accession No. P30524; and Satozawa et al, GenBank Accession No. T02965). None of the enzymes from these other plants have a histidine at amino acid 333, and it is not clear that mutating the amino acid that is present at position 333 would result in heat stable enzymes.

Lastly, the transformation of whole plants with genes encoding altered plant AGP subunits for increased heat resistance is unpredictable. Lafta et al (1995, Plant Physiol. 109:637-643) teach that in potato there is a lack of relationship between enzyme stability and heat resistance in the whole plant (pg 641, right column, last paragraph to pg 642, left column, 1st full paragraph). Greene et al (1998b, Proc. Natl. Acad. Sci. USA 95:13342-13347) teach that in wheat, starch synthase is responsible for heat-induced seed weight loss (pg 13342, right column, 1st full paragraph). Additionally, transgenic plants containing AGP genes behave unpredictably in other ways. Sweetlove et al (1996, Biochem. J. 320:493-498) found no differences in starch

content, tuber number, tuber weight, or metabolite content between potatoes transformed with a gene encoding AGP and control plants, even though the activity of the enzyme was four-fold higher in the transformed plants (pg 495, entire pg, and pg 497, right column, paragraph 3).

6. Claims 1, 42-51 and 53-84 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 8 August 2003, as applied to claims 1, 3, 5-26 and 29-41. Applicant's arguments filed 11 December 2003 have been fully considered but they are not persuasive.

Applicant urges that claim 1 recites that the protein is a plant ADP-glucose pyrophosphorylase large subunit (response pg 12).

This is not found persuasive because description of the function of the protein encoded by the polynucleotide does not describe the sequence of the polynucleotide.

Applicant urges that sequences of large subunit AGP for numerous plant species were well known in the art prior to the earliest effective filing date of the instant application and that a plant need not teach what is well known in the art (response pg 12-13).

This is not found persuasive. Applicant provides no evidence that the sequences of nucleic acid encoding the ADP large subunit from all of oats, sorghum, lily, millet, pea, alfalfa, chickpea, chicory, clover, kale, lentil, soybean, tobacco, sweet potato, radish, cabbage, rape, apple tree and lettuce were known prior to the earliest effective filing date of the instant application.

Applicant urges that the sequence alignment in Figure 2 the amino acids for wheat and barley corresponding to His 33 of maize large ADP were known in the art (response pg 13).

This is not found persuasive because the claims are drawn to mutations at amino acids other than His^{333}.

Applicant urges that Figure 2 shows there is extensive homology between maize, wheat and barley sequences (response pg 13).

This is not found persuasive because no description is provided for the sequences of nucleic acids encoding the ADP large subunit from all of oats, sorghum, lily, millet, pea, alfalfa, chickpea, chicory, clover, kale, lentil, soybean, tobacco, sweet potato, radish, cabbage, rape, apple tree and lettuce.

7. Claims 1 and 42-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections. The rejection is repeated for the reasons of record as set forth in the Office action mailed 8 August 2003, as applied to claims 1, 3, 5-26 and 29-41. Applicant's arguments filed 11 December 2003 have been fully considered but they are not persuasive.

Claim 1 is indefinite in its recitation of "biologically-active fragment". It is not clear what the biological activity of the fragment is - is it the same as the mutant polypeptide or is it some other biological activity?

Applicant urges that the phrase refers to a fragment of the mutant polypeptide that has the same or substantially the same biological activity as the full-length mutant protein (response pg 13).

This is not found persuasive because the claim does not make it clear that the biological activity of the fragment is that of the mutant polypeptide. It is also not clear how different substantially the same biological activity is from the same biological activity.

Claims 42-44, 47-49, 55-59, 66-70 and 79-83 are indefinite in their recitation of "amino acid corresponding to position(s)". It is unclear what it means for an amino acid to correspond to a position.

Applicant urges that this phrase is definite and one of skill in the art would understand the metes and bounds of the claims (response pg 13).

This is not found persuasive. An amino acid cannot correspond to a position, although it can correspond to an amino acid at a position.

Double Patenting

8. Claims 1, 42 and 50-52 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,069,300. The rejection is repeated for the reasons of record as set forth in the Office action mailed 8 August 2003, as applied to claims 1, 3, 5, 30 and 37-39. Applicant's arguments filed 11 December 2003 have been fully considered but they are not persuasive.

Applicant urges that the new claims are not obvious over those of the cited patent (response pg 14).

This is not found persuasive because a nucleic acid encoding a maize large AGP subunit mutant with a $His^{333} \rightarrow Tyr^{333}$ mutation, wherein the mutant protein has increased heat stability, as claimed in the issued patent, is a species of the genus of nucleic acids encoding a maize large AGP subunit mutant with a mutation in His^{333} that confers increased heat stability, as claimed in the instant application.

9. Claims 1, 42, 50-52, 58-63, 69-70, 72-75, 78 and 82-83 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 20-30 and 48-54 of U.S. Patent No. 6,403,863. The rejection is modified from the rejection set forth in the Office action mailed 8 August 2003, as applied to claims 1, 3, 5, 15-17, 20-23, 26, 30 and 37-39. Applicant's arguments filed 11 December 2003 have been fully considered but they are not persuasive.

Although the conflicting claims are not identical, they are not patentably distinct from each other because nucleic acids encoding maize large AGP subunit mutants, including ones with substitutions of $His^{333} \rightarrow$ an amino acid that confers increased heat stability and $His^{333} \rightarrow Tyr^{333}$, or substitutions of $Glu^{324} \rightarrow Lys^{324}$, $Ala^{359} \rightarrow Val^{359}$ and $Ala^{396} \rightarrow Val^{396}$, a method for using the nucleic acids to increase heat resistance in a plant, including in maize, wheat, rice, and barley, and plants, plant tissues and seeds so obtained, as claimed in the issued patent, are a species of the genus of nucleic acids encoding a large AGP subunit mutant with a mutation in His^{333} that confers increased heat stability, or substitutions of $Glu^{324} \rightarrow Lys^{324}$, $Ala^{359} \rightarrow Val^{359}$ and $Ala^{396} \rightarrow Val^{396}$, a method for using the nucleic acids to increase heat resistance in a plant, including in maize, wheat, rice, and barley, and plants, plant tissues and seeds so obtained, as claimed in the instant application.

Applicant urges that the new claims are not obvious over those of the cited patent (response pg 14).

This is not found persuasive because nucleic acids, methods for using them to increase heat resistance in a plant and plants, plant tissues and seeds so obtained, as claimed in the issued patent, are a species of the genus of nucleic acids, methods for using them to increase heat resistance in a plant, including in maize, wheat, rice, and barley, and plants, plant tissues and seeds so obtained, as claimed in the instant application.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (703) 308-0198.

Anne R. Kubelik, Ph.D.
February 20, 2004

ANNE KUBELIK
PATENT EXA...